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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT	PAPER NUMBER
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1637

NOTIFICATION DATE	DELIVERY MODE
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08/07/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/556,903	Applicant(s) HIRAO ET AL.	
	Examiner ANGELA BERTAGNA	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 9-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Applicant's response filed on April 29, 2009 is acknowledged. Claims 1-28 are currently pending. In the response, Applicant amended claim 1. Claims 9-28 remain withdrawn as being drawn to a non-elected invention.

Applicant's amendment has overcome all of the previously made rejections and objections, and therefore, they have been withdrawn. The following are new grounds of rejection necessitated by Applicant's amendment. Applicant's arguments filed on April 29, 2009 that remain pertinent to the new grounds of rejection have been fully considered, but they were not persuasive for the reasons set forth in the "Response to Arguments" section. Accordingly, this Office Action is made **FINAL**.

Election/Restrictions

2. This application contains claims 9-28 drawn to an invention nonelected with traverse in the reply filed on August 22, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claim Objections

3. Claim 1 is objected to because of the following informalities: This claim appears to contain a typographical error in line 7 where "a food or the food ingredient" is recited. It would appear that "the food or food ingredient" was intended.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8 are vague and indefinite, because the newly added equation in independent claim 1 is unclear. Claim 1 recites calculating the amount of the plant belonging to the specific plant genus contained in the sample using the following equation:

$$\text{Amount} = F_s / L_s \times L_o / F_o \times 1,000,000.$$

This equation is unclear, because it does not indicate the order in which the calculation is to be done. In other words, the equation as written above could be calculated in two ways:

$$\text{A. Amount} = \left[\frac{\frac{F_s}{L_s \times L_o}}{F_o \times 1,000,000} \right]$$

or

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$$\text{B. Amount} = \left(\frac{Fs}{Ls} \right) \times \left(\frac{Lo}{Fo} \right) \times 1,000,000$$

The above formulas will give completely different results, and accordingly, it is entirely unclear from the claim language as to how the amount is to be calculated. Accordingly, claims 1-8 are vague and indefinite. For examination purposes, both of the above possibilities have been considered with respect to the prior art.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1-3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. (US 2003/0207298 A1; cited previously) in view of Haugland et al. (Molecular and Cellular Probes (1999) 13: 329-340; newly cited).

These claims are drawn to methods of quantifying a plant belonging to a specific plant genus in a food ingredient or food sample comprising quantitative PCR.

Hirao teaches PCR-based methods for detecting a target plant genus in a food ingredient (see abstract, paragraph 5, and paragraphs 13-15 for a general description). Hirao teaches that the disclosed methods are especially suitable for detecting the presence of allergenic plants, such as plants of the genus *Fagopyrum*, in food samples or food ingredients (paragraphs 5-7).

Regarding claim 1, Hirao teaches a method of detecting a plant belonging to a specific plant genus in a food or a food ingredient by a PCR method, comprising:

(a) extracting genomic DNA from a food ingredient or food sample to be tested that is suspected of containing the specific plant genus to be tested (see pages 8-9, paragraphs 102-125, for example)

(b) conducting PCR using a primer pair specific for the specific plant genus to be tested (see, for example, page 9, paragraphs 126-128)

(c) detecting the specific plant genus in a food or food ingredient (see, for example, page 9, paragraphs 128-138).

Regarding claim 6, Hirao teaches that the specific plant genus is *Fagopyrum*, *Arachis*, *Glycine*, or *Triticum* (see paragraphs 31 and 39-46, for example). Hirao also teaches detecting plants in the *Fagopyrum* genus at pages 8-14 and 23-26, detecting plants in the *Arachis* genus at

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pages 14-23 and 26-34, detecting plants in the *Triticum* genus at pages 34-40, and detecting plants in the *Glycine* genus at pages 40-44.

Regarding claim 8, Hirao teaches detecting the plant genus *Fagopyrum* via PCR (see Examples 1-2 on pages 6-14). Hirao also teaches that the instant SEQ ID NO: 14 and SEQ ID NO: 15 are useful primers for the specific amplification of the *Fagopyrum* genus (see paragraphs 40 and 189-190). Hirao also teaches that the complement of the instant SEQ ID NO: 64 (*i.e.* SEQ ID NO: 12) is a useful primer for the specific amplification of the *Fagopyrum* genus (paragraph 40).

Hirao does not teach performing quantitative real-time PCR using fluorogenic probes to determine the copy number of DNA from the plant genus to be tested as required by claims 1-3. Hirao also does not teach that the disclosed PCR detection method uses a sample for correction comprising a known amount of a standard plant sample and a known amount of the plant sample to be tested or that a known amount of the standard plant sample is added to the food ingredient or food sample to be tested as required by claim 1.

Haugland teaches a method for detecting the fungal pathogen *Stachybotrys chartarum* comprising real-time PCR with fluorogenic probes (see abstract and pages 330-334).

Regarding claim 1, Haugland teaches that the disclosed method comprises adding a known amount of a standard fungal sample (*Geotrichum candidum*) to the sample to be tested and measuring the copy number of the standard fungal species and the copy number of the target fungal species by real-time PCR (see pages 330-332). Haugland further discloses that the method comprises preparation of a sample for correction (*i.e.* the calibrator) containing a known amount of the target fungal species (*Stachybotrys chartarum*) and a known amount of the

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standard fungal species (*Geotrichum candidum*) and determining the copy number of the target and standard fungal species by real-time PCR (pages 330-332). Haugland further teaches that the standard fungal species is added to the sample for correction and the test sample in the same amount (pages 330 and 332). Haugland teaches that "Ratios of target sequences determined in the test and calibrator samples were then multiplied by the known quantities of *S. chartarum* conidia in the calibrator samples to obtain estimates of the absolute quantities of these conidia in the test samples (page 332, column 2)." It is noted that conducting the above analysis as taught by Haugland results in the calculation step recited in the instant claim 1 with the exception of a conversion of the resulting amount to parts per million (ppm). Haugland further teaches that conducting the above analysis allows the experimenter to normalize the calculated amounts of a target nucleic acid for potential sample to sample variations in DNA extraction efficiency (see page 334, column 2).

Regarding claims 2 and 3, Haugland teaches detecting *Stachybotrys chartarum* via real-time PCR amplification and detection with TaqMan fluorogenic probes (see abstract and pages 330-334). Haugland teaches that real-time PCR and detection with fluorogenic probes can be performed using a device that detects and quantitatively measures the signal related to the production of amplified products in an automated fashion (page 330, column 1). Haugland also teaches that real-time PCR amplification and detection with TaqMan fluorogenic probes is faster, simpler, more accurate, and less labor-intensive than conventional PCR amplification and detection methods (page 330, column 1).

It would have been *prima facie* obvious to apply the teachings of Haugland to the method of Hirao. An ordinary artisan would have been motivated to substitute real-time PCR

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amplification and detection with fluorogenic probes as taught by Haugland for the conventional PCR amplification and detection method taught by Hirao, since Haugland taught that real-time PCR amplification and detection with fluorogenic probes was faster, simpler, more accurate, and less labor-intensive than conventional PCR amplification and detection methods (page 330, column 1). An ordinary artisan also would have been motivated to utilize a sample for correction and perform the associated analysis as taught by Haugland and described above using a standard plant sample in order to obtain the ability to control for sample to sample variations in DNA extraction efficiency. An ordinary artisan also would have been motivated to express the resulting amount in any suitable units, such as the claimed parts per million, recognizing that the units were not critical and should be selected as a matter of design choice. An ordinary artisan would have had a reasonable expectation of success in applying the teachings of Haugland to the method disclosed by Hirao, since both methods were directed to specific amplification and detection of target nucleic acids. Thus, the methods of claims 1-3, 6, and 8 are *prima facie* obvious over Hirao in view of Haugland.

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. (US 2003/0207298 A1; cited previously) in view of Haugland (Molecular and Cellular Probes (1999) 13: 329-340; newly cited) and further in view of Palacios et al. (Molecular Phylogenetics and Evolution (2000) 14(2): 232-249; cited previously).

Claims 4 and 5 are drawn to the method of claim 1, wherein the standard plant belongs to a plant species other than upland weeds and food crops, specifically statice.

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The combined teachings of Hirao and Haugland result in the methods of claims 1-3, 6, and 8, as discussed above.

These references do not teach that the standard plant is static.

Palacios analyzed the nuclear ITS sequences from the *Limonium* (static) genus by RFLP and PCR amplification followed by sequencing (pages 233-237).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to use static as the standard plant when practicing the method resulting from the combined teachings of Hirao and Haugland. An ordinary artisan would have been motivated to use any readily available plant, such as the static taught by Palacios, when practicing the method resulting from the combined teachings of Hirao and Haugland, recognizing that the choice of the standard was not critical to practice of the invention provided that DNA could be extracted and amplified therefrom. In other words, the ordinary artisan would have recognized that the static plant samples taught by Palacios was suitable for use as a standard plant sample, and therefore, would have been motivated to utilize it as such with a reasonable expectation of success. As noted in MPEP 2144.07, it is *prima facie* obvious to select a known material based on its suitability for the intended purpose in the absence of unexpected results. In this case, no evidence has been presented to suggest that the use of static as the standard plant sample is associated with unexpected results, and therefore, the methods of claims 4 and 5 are *prima facie* obvious over Hirao in view of Haugland and further in view of Palacios.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. (US 2003/0207298 A1; cited previously) in view of Haugland (Molecular and Cellular Probes (1999)

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13: 329-340; newly cited) and further in view of Palacios et al. (Molecular Phylogenetics and Evolution (2000) 14(2): 232-249; cited previously) and further in view of GenBank Accession Number AJ222860 (December 2000; cited previously) and further in view of Buck et al. (BioTechniques (1999) 27: 528-536; cited previously).

Claim 7 is drawn to the method of claim 2, wherein the standard plant is statice, wherein SEQ ID NO: 57-58 are used as a primer pair in the quantitative PCR method, and wherein SEQ ID NO: 59 is used as a probe in the quantitative PCR method.

The combined teachings of Hirao and Haugland result in the methods of claims 1-3, 6, and 8, as discussed above.

These references do not teach that the standard plant is statice or the use of the claimed primer pair and oligonucleotide probe.

Palacios analyzed the nuclear ITS sequences from the *Limonium* (statice) genus by RFLP and PCR amplification followed by sequencing (pages 233-237).

Palacios does not teach using the claimed oligonucleotides as amplification primers or probes.

GenBank Accession Number AJ222860 teaches the partial sequence of the 18S and 26S rRNA genes, ITS1, and ITS2 of *Limonium sinuatum*, which is a statice. The instantly claimed sequences are contained in this nucleic acid (see alignments below).

SEQ ID NO: 57

Qy	1	TTGGACGTGTATCCCTTGTGGTTC	24
Db	105	TTGGACGTGTATCCCTTGTGGTTC	128

SEQ ID NO: 58

Qy	1	CACGAAGGTGAAAGTTGCGTTCAT	24
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                |||
Db          205 CACGAAGGTGAAAGTTGCGTTCAT 182

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SEQ ID NO: 59

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Qy          1 TGTGCGACGCGGAATG 16
                |||
Db          155 TGTGCGACGCGGAATG 170

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Buck analyzed the effect of primer design strategy on the performance of DNA sequencing primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that every single primer worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, every single control primer functioned as well (see page 533, column 1). Buck expressly states “The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2).” Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to use static as the standard plant when practicing the method resulting from the

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combined teachings of Hirao and Haugland. An ordinary artisan would have been motivated to use any readily available plant, such as the statice taught by Palacios, when practicing the method resulting from the combined teachings of Hirao and Haugland, recognizing that the choice of the standard was not critical to practice of the invention provided that DNA could be extracted and amplified therefrom. In other words, the ordinary artisan would have recognized that the statice plant samples taught by Palacios were suitable for use as the standard plant sample, and therefore, would have been motivated to utilize them as such with a reasonable expectation of success. As noted in MPEP 2144.07, it is *prima facie* obvious to select a known material based on its suitability for the intended purpose in the absence of unexpected results.

It also would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to design amplification primers and probes based on any stretch of sequence contained in GenBank Accession Number AJ222860 (for example, the claimed SEQ ID NO: 57-59) in order to amplify and detect statice using the quantitative PCR method suggested by the teachings of Hirao, Haugland, and Palacios. Since Buck clearly demonstrated the equivalence of primer sequences, the ordinary biochemist would have anticipated a reasonable level of success in using any amplification primers and probes in the method resulting from the combined teachings of Hirao, Haugland, and Palacios. Therefore, absent any secondary considerations, the use of the claimed oligonucleotides in the method resulting from the combined teachings of Hirao, Haugland, and Palacios is *prima facie* obvious in light of the teachings of GenBank Accession No. AJ222860 and Buck.

Attention is also directed to *KSR Int'l Co. v. Teleflex Inc.* (550 U.S._____, 127 S. Ct. 1727 (2007)) where the Supreme Court determined that “a person of ordinary skill has good reason to

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pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103 (*KSR*, 550 U.S. at ____, 82 USPQ2d at 1397).”

In this case, as discussed above, the sequence of the 18S and 26S rRNA genes, ITS1 and ITS2 regions of the statice plant *Limonium sinuatum* was well known in the art as demonstrated by GenBank Accession No. AJ222860. This prior art would have suggested to the ordinary artisan a finite number of possible oligonucleotide primers and probes. An ordinary artisan would have expected predictable results, and thus would have had a reasonable expectation of success, in pursuing this finite number of possible oligonucleotides suggested by the prior art of GenBank Accession No. AJ222860, since oligonucleotide synthesis methods were well known in the art at the time of invention and also since Buck clearly demonstrated the equivalence of primer sequences. Thus, the method of claim 7 is *prima facie* obvious over the cited references in the absence of secondary considerations.

Response to Arguments

9. As noted above, all of the previously made rejections have been withdrawn in view of the claim amendments. Some of Applicant's arguments filed on April 29, 2009 remain pertinent to the new grounds of rejection made above. These arguments have been fully considered, but they were not persuasive.

Applicant first argues that the claimed methods provide unexpected benefits compared to the prior art, specifically improved accuracy, sensitivity, specificity, reliability, and reproducibility (see page 16).

This argument was not persuasive, because as noted in MPEP 716.01(b), attorney arguments cannot be substituted for evidence where evidence is necessary. In this case, Applicant has made only a general allegation as to unexpected results that does not appear to be supported by comparison with the closest prior art or establishment of a nexus between the claimed invention and any evidence of unexpected results. Also, the results of the working examples described in the specification are not commensurate in scope with the claimed invention, because the claimed methods are not limited to a particular plant genus or to the specific reaction conditions used in the disclosed examples. There is no indication that the results obtained in the working examples would necessarily extend over the full scope of the claimed methods, which encompass the detection of any plant genus using any suitable standard plant standard for correction under unspecified quantitative PCR reaction conditions. As noted in MPEP 716, any evidence of unexpected results must be considered with respect to the closest prior art, clearly establish a nexus between the features of the claimed invention and the unexpected results and be commensurate in scope with the claimed invention.

Applicant also argues that oligonucleotides taught by Palacios cannot be used to amplify only static because they are universal primers (page 17). This argument was not persuasive, because the Palacios reference is cited to provide evidence that any plant of known sequence would have been suitable for use as a standard in the methods resulting from the combined teachings of Hirao and Haugland in the absence of secondary considerations.

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Applicant's remaining arguments filed on April 29, 2009 have been considered, but they are moot in view of the new grounds of rejection presented above.

Conclusion

10. No claims are currently allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

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